self-care, or usual activities; 15.8% and 16.5% reported pain/discomfort and anxiety/depression, respectively. The mean (standard deviation) global health score was 83.5 (13.3) on a 0 (worst) to 100 (best) scale. Independent predictors of reporting any of the EQ-5D health problems included female gender, BMI 25-30 kg/m2, presence of comorbidity (hypertension, hyperlipidemia, etc.), family history of liver cancer, albumin <28g/L, and HBeAg positive. Alcohol drinking, a diagnosis of CHB for >15 years, and presence of comorbidity were independent predictors of a lower global health score, with the effect size ranging between 1 and 4 points. **CONCLUSIONS:** CHB characteristics showed some association with patient-reported health problems, but their association with general health perception was minimal. The modest relationship between clinical and patient-reported outcomes measures supports the assessment of patient-reported outcomes in patients with CHB.

PGI30

RIBAVIRIN DOES NOT IMPACT HEALTH-RELATED QUALITY OF LIFE (HRQOL) IN PATIENTS ON OMBITASVIR/ PARITAPREVIR /RITONAVIR AND DASABUVIR AT THE END OF 12-WEEK TREATMENT IN TREATMENT-NAÏVE ADULTS WITH GENOTYPE 1A (GT1A) CHRONIC HEPATITIS C

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OBJECTIVES: The impact on patient HRQoL of including ribavirin (RBV) in interferon-free hepatitis C virus (HCV) treatment has not been determined. We assessed the HRQoL impact of an all-oral HCV therapy, ombitasvir/paritaprevir/ritonavir and dasabuvir (OBV/PTV/r+DSV), with and without RBV in treatment naïve, non-cirrhotic, GT1a adults at the end of 12-week treatment in Phase 3 PEARL-IV trial. **METHODS:** HCV patients were randomized in a 1:2 ratio to OBV/PTV/r+DSV with RBV or OBV/PTV/r+DSV without RBV and treated during a 12-week double-blind period. HRQoL was assessed using the SF-36v2 Health Survey (SF-36) which was administered to patients at baseline, during treatment, at end of treatment (EOT) and at post-treatment (PT) visits. Physical Component Summary (PCS) and Mental Component Summary (MCS) scores were calculated for the SF-36. The statistical significance of differences between treatment groups in mean change from baseline to EOT was assessed. **RESULTS:** The analysis included 100 patients on OBV/PTV/r+DSV with RBV and 205 on OBV/PTV/r+DSV without RBV. At EOT, mean±SD decrements from baseline PCS and MCS scores were observed in the RBV group (change of -0.6±7.19 in PCS and -2.9±10.55 in MCS) while small increases were observed in the non-RBV group (change of +0.9±7.01 in PCS and +0.3±10.09 in MCS). The difference in mean change from baseline to EOT did not reach statistical significance for either PCS (p-value=0.105) or MCS (p-value=0.063). At PT week 24, mean changes from baseline were 2.4±5.19 in PCS and 2.6±6.99 in MCS in the RBV group, and 2.2±7.00 in PCS and 2.0±10.94 in MCS in the non-RBV group. **CONCLUSIONS:** At the end of 12-week treatment in PEARL-IV, the addition of RBV to the interferon-free all-oral OBV/PTV/r+DSV regimen did not have a significant impact on patient HRQoL in treatment-naïve GT1a patients. After treatment, PCS and MCS scores for both treatment groups showed similar improvement over baseline.

PGI31

HEALTH-RELATED QUALITY OF LIFE (HRQOL) IN PATIENTS ON OMBITASVIR/ PARITAPREVIR /RITONAVIR AND DASABUVIR AT THE END OF 12-WEEK TREATMENT IN TREATMENT-NAÏVE ADULTS WITH GENOTYPE 1B (GT1B) CHRONIC HEPATITIS C

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OBJECTIVES: An all-oral HCV therapy, ombitasvir/paritaprevir/ritonavir and dasabuvir (OBV/PTV/r+DSV), without ribavirin (RBV), has been approved by the Food and Drug Administration (FDA) for treatment of treatment naïve, non-cirrhotic, GT1b adults. We report the HRQoL impact of OBV/PTV/r+DSV, with and without RBV, after 12-week treatment in the Phase 3 PEARL-III trial. **METHODS:** HCV patients were randomized in a 1:1 ratio to OBV/PTV/r+DSV with RBV or OBV/PTV/r+DSV without RBV and treated during a 12-week double-blind period. HRQoL was assessed using the SF-36 v2 Health Survey (SF-36) which was administered to patients at baseline, during treatment, at end of treatment (EOT) and at post-treatment (PT) visits. Physical Component Summary (PCS) and Mental Component Summary (MCS) scores were calculated for the SF-36. The statistical significance of differences between treatment groups in mean change from baseline to EOT was assessed. **RESULTS:** The analysis included 210 patients on OBV/PTV/r+DSV with RBV and 209 on OBV/PTV/r+DSV without RBV. Among non-cirrhotic subjects with GT1b infection who were treated with OBV/PTV/r+DSV without RBV, almost no decrements from baseline PCS or MCS scores were observed at EOT (changes [mean±SD] of -0.1±6.71 in PCS and -0.1±9.09 in MCS). The decrements OBV/PTV/r+DSV with RBV were numerically larger (-0.5±6.80 in PCS and -1.4±9.15 in MCS); however, differences from the non-RBV group were not statistically significant for either PCS or MCS (p-value=0.348 in PCS and p-value=0.150 in MCS). At PT week 24, mean changes from baseline were 1.0±6.20 in PCS and 1.9±8.40 in MCS in the non-RBV group 0.9±6.04 in PCS and 1.8±7.40 in MCS in the RBV group. **CONCLUSIONS:** At the end of 12-week treatment in PEARL-III, the interferon-free all-oral OBV/PTV/r+DSV regimen in treatment-naïve GT1b patients had negligible impact on patient HRQoL, regardless of whether RBV was co-administered. After treatment, PCS and MCS scores for both treatment groups showed similar improvement over baseline.

PGI32

DEVELOPMENT AND VALIDATION OF A CLOSTRIDIUM DIFFICILE QUALITY OF LIFE QUESTIONNAIRE

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OBJECTIVES: Patients with Clostridium difficileinfection (CDI) can experience long-term symptoms that resemble a chronic disease state. Despite this, a health-related quality of life (HRQOL) instrument specific for patients with CDI does not exist. The goal of this study was to develop and validate a disease specific instrument to assess HRQOL in patients with CDI. **METHODS:** A systematic literature review was conducted to identify HRQOL instruments and questions related to general health (n=3) or gastrointestinal disease (n=13) related to CDI HRQOL. Removing duplicate questions and using direct patient (n=10) or clinician (n=10) interviews, a 36-item survey specific to CDI HRQOL was developed. Test-retest and acceptability of item selection was tested on 20 CDI patients and 20 healthy volunteers. The Cdiff36 HRQOL survey was then tested using 100 patients with CDI and compared to the RAND Short-Form 36 (SF-36) Health Survey. Domains containing questions with a correlation coefficient of >0.7 were considered acceptable. To compare population average scores for patients with CDI, the SF-36 was also administered to 82 patients given broad-spectrum antibiotics. **RESULTS:** SF-36 scores were significantly higher in healthy controls (72±22) compared to patients on broad-spectrum antibiotics (54±12) or patients with CDI (43±17); p<0.05 each vs. control. The final version of the Cdiff36 contained six domains: daily activities (4 items), anxiety (3 items), diet (3 items), sleep (2 items), discomfort (6 items), health perception (6 items), dysphoria (6 items), relationship (2 items), and social interaction (3 items). CDiff36 scores correlated significantly based on recurrence vs. primary CDI as well as time since last episode (p<0.05, each). Cdiff36 scales also correlated significantly with the SF-36. **CONCLUSIONS:** The properties of the Cdiff36 should make it appropriate to assess changes over time in HRQOL in patients with CDI. Future language translations and validation will be required for global use of the CDiff36.

PGI33

SYSTEMATIC REVIEW OF QUALITATIVE STUDIES TO IDENTIFY HEALTH RELATED QUALITY OF LIFE CONSTRUCTS REPORTED BY PATIENTS WITH HEPATITIS C

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OBJECTIVES: The Food and Drug Administration's (FDA) clinical trial guidelines for development of patient reported outcome (PRO) instruments recommends deriving the PRO concepts from the target population using qualitative research. Since the PRO instruments currently used in clinical trials of hepatitis C (HCV) patients are not developed specifically for this patient population, the FDA's recommendation is not fulfilled. The purpose of this study was to identify a comprehensive list of health related quality of life (HRQoL) themes that may be unique to HCV by reviewing qualitative studies of HCV patients. **METHODS:** Ovid Medline, Ovid Embase, Ovid PsycINFO, and PubMed were searched for peer-reviewed journals from 1946 to 2012. Inclusion criteria required primary studies to include HCV patients; be published in English; and used qualitative methods to report an aspect of the HCV experience. Studies were excluded if secondary data was used or there were proxy views. Included studies were graded on study quality using the Qualitative Assessment and Review Instrument. Eligible studies were then analyzed using meta-synthesis; findings from individual studies were grouped into themes which were combined to generate HRQoL domains. **RESULTS:** Ten studies met the inclusion/exclusion criteria and the quality assessment criteria and were included for review. Eleven themes were identified: physical symptoms, physical activities, guilt, stigma, emotional distress, psychological behavior, social relationship, social activities, work function, sexual function, and cognitive function. The type of themes identified in each study varied by the focus of the primary study and the analytical framework used in the qualitative studies. The themes were further grouped into six HRQoL domains: physical, psychological/emotional, social, work, sexual, and cognitive functionality. **CONCLUSIONS:** The systematic review represents a useful starting point in the critical appraisal of the PRO instruments used for clinical trials in HCV patients.

GASTROINTESTINAL DISORDERS – Health Care Use & Policy Studies

PGI34

DO PHYSICIANS CHANGE THEIR PRESCRIPTIONS IN RESPONSE TO FINANCIAL INCENTIVES

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OBJECTIVES: We assessed the impact on prescription behaviors and drug expenditures of an outpatient prescription incentive program in South Korea that provides financial incentives to primary care physicians for less prescription of medicines. **METHODS:** We focused on drugs for ulcer or gastro-esophageal reflux disease. National Health Insurance claims data for years 2009~2012 were extracted from 1,625 clinics. A clinic-level random effects model was used. **RESULTS:** The overall impact of the program on drug expenditure was not significant. However, clinics in general medicine showed a lower prescription rate (-0.8 percentage points), number of medicines prescribed (-0.02), prescription duration (-0.15 days), and monthly drug expenditure (-740 won) per claim after the policy. Small clinics had lower drug expenditure (-650 won) and prescription duration (-0.76 days), while large clinics and those in group practice had higher prescription rate (+1.5 and 2.5 percentage points, respectively) and number of medicines prescribed (+0.03, group practice only) after the policy. **CONCLUSIONS:** The outpatient prescription incentive program worked as intended only in subgroups of minor clinics for the target medicines.

PGI35

A DESCRIPTIVE ANALYSIS OF A REAL-WORLD POPULATION WITH CHRONIC HEPATITIS C (CHC) TREATED WITH SIMEPREVIR (SMV)- AND/OR SOFOSBUVIR (SOF)-BASED REGIMENS: FINDINGS FROM A US PAYER DATABASE

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